## UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY	
AVERAGE WHOLESALE PRICE LITIGATION	
THIS DOCUMENT RELATES TO:	MDL NO. 1456
The City of New York v. Abbott Laboratories, Inc., et al. (S.D.N.Y. No. 04-CV-06054)	Civil Action No. 01-12257-PBS
County of Albany v. Abbott Laboratories, Inc., et al.	Subcategory Case No. 03-10643-PBS
(N.D.N.Y. No. 05-CV-00425)	Judge Patti B. Saris
County of Allegany v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06231)	
County of Broome v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00456)	STATEMENT OF UNDISPUTED
County of Cattaraugus v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06242)	MATERIAL FACTS IN SUPPORT OF DEFENDANT SMITHKLINE BEECHAM CORPORATION,
County of Cayuga v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00423)	D/B/A GLAXOSMITHKLINE'S ("GSK's") MOTION FOR
County of Chautauqua v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06204)	PARTIAL SUMMARY JUDGMENT IN THE NEW YORK COUNTY CASES
County of Chemung v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06744)	
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County of Greene v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00474)

County of Herkimer v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00415)

County of Jefferson v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00715)

County of Lewis v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00839)

County of Madison v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00714)

County of Monroe v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06148)

County of Nassau v. Abbott Laboratories, Inc., et al. (E.D.N.Y. No. 04-CV-5126)

County of Niagara v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06296)

County of Oneida v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00489)

County of Onondaga v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00088)

County of Ontario v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06373)

County of Orange v. Abbott Laboratories, Inc., et al. (S.D.N.Y. No. 07-CV-2777)

County of Orleans v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06371)

County of Putnam v. Abbott Laboratories, Inc., et al. (S.D.N.Y. No. 05-CV-04740)

County of Rensselaer v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00422)

County of Rockland v. Abbott Laboratories, Inc., et al. (S.D.N.Y. No. 03-CV-7055)

County of Saratoga v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00478)

County of Schuyler v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06387)

County of Seneca v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06370)

County of St. Lawrence v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00479)

County of Steuben v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06223)

County of Suffolk v. Abbott Laboratories, Inc., et al. (E.D.N.Y. No. CV-03-229)

County of Tompkins v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00397)

County of Ulster v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 06-CV-0123)

County of Warren v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00468)

County of Washington v. Abbott Laboratories, Inc., et al. (N.D.N.Y. No. 05-CV-00408)

County of Wayne v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06138)

County of Westchester v. Abbott Laboratories, Inc., et al. (S.D.N.Y. No. 03-CV-6178)

County of Wyoming v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 03-CV-6379)

County of Yates v. Abbott Laboratories, Inc., et al. (W.D.N.Y. No. 05-CV-06172)

## GSK's STATEMENT OF UNDISPUTED MATERIAL FACTS

SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK"), hereby

submits this Statement of Undisputed Material Facts in support of its Motion for Partial

Summary Judgment in the above-captioned cases ("GSK's Statement of Facts" or GSK's SOF"). The following facts are undisputed:

## A. GSK's List Price Reporting

- 1. GSK and its predecessors have, for the entire 1997-2005 period now at issue in this case, reported a "Wholesale Acquisition Cost" ("WAC"), or a WAC equivalent, to First DataBank and the other commercial price reporting services. GSK's 1997-2005 price reporting conventions can be broken into three time periods, as follows:
- a. Since shortly after the merger that formed GSK in 2001, GSK has reported a WAC, and only a WAC (*i.e.*, no AWP or anything like it), for all of its prescription pharmaceuticals. Affidavit of David A. Moules dated February 25, 2004 at ¶ 5, appended as Ex. 3 (hereinafter "Moules 2004 Aff."). Since its formation, GSK has specifically defined its reported "WAC" in its routine pricing communications to First Databank and its customers as "the listed price to wholesalers and warehousing chains, not including prompt pay, stocking or distribution allowances, or other discounts, rebates, or chargebacks." *Id.*; see also GSK price reporting letters, appended as Ex. 5.
- b. Prior to the merger that formed GSK in early 2001 (and since before 1997), GSK predecessor Glaxo Wellcome, Inc. ("GW") reported a WAC-equivalent that it called "NWP" ("Net Wholesale Price"). Affidavit of GSK Vice President David A. Moules dated September 25, 2006, at ¶ 4 (hereinafter "Moules 2006 Aff."), appended as Ex. 6. GW included the following definition of this WAC-equivalent

Mr. Moules has served as GSK's Rule 30(b)(6) deponent on price reporting issues, and his May 8, 2007 deposition in the Alabama AWP case was cross-noticed in this case by Stipulation. See Stipulation dated April 18, 2007 at ¶ 6, appended as Ex. 4; see also Affidavit of Frederick G. Herold, Esq. (hereinafter "Herold Aff."), appended hereto as Exhibit 1, at ¶¶ 2-3. All exhibits referred to herein are appended, and all exhibits are briefly described and authenticated by the Herold Affidavit appended as Exhibit 1, except for the Affidavit of Dr. Eric M. Gaier, an expert affidavit prepared in support of this Motion, which is appended as Exhibit 2.

in its routine pricing communications, starting in 1999: "List price to wholesalers and warehousing chains, not including prompt pay, stocking or distribution allowances, or other discounts, rebates or chargebacks." See GW price reporting letters, appended as Ex. 7. In addition, in a proposed Medicaid pricing contract submitted by GSK predecessor Glaxo, Inc. to the New York Medicaid Program as early as 1990, Glaxo explicitly defined its reported "Net Wholesale Price" as "the wholesale list price." See Market Adjustment Agreement at 2, appended as Ex. 9; Herold Aff. at ¶¶ 5, 6, 8 (Ex. 1).

c. Prior to the 2001 merger (and since before 1997), GSK's other predecessor -- SmithKline Beecham Corporation ("SB") -- reported a WAC-equivalent that it called "WPP" ("Wholesaler Purchase Price"). Moules 2006 Aff. at ¶ 5 (Ex. 6). SB defined this WAC-equivalent in its routine pricing communications, starting in 2000, as follows: "SB's price to SB's wholesaler class of trade, without taking into account prompt pay discounts or other pricing or promotional concessions paid to wholesalers, or chargebacks paid to wholesalers on account of purchases by wholesalers' end user customers." See SB price reporting letters, appended as Ex. 8. Before SB became GSK in 2001, it also reported a "Suggested List Price" ("SLP"), which it defined as the "non-binding suggested resale price to end user purchasers who do not purchase under special contractual arrangements. Actual end user acquisition costs may be lower than the Suggested List Price, depending on wholesaler mark-ups, chargebacks or other pricing concessions." See SB price reporting letters, appended as Ex. 8. The amount of the SLP was typically 1.25 times the WPP. Moules 2006 Aff. at ¶ 5 (Ex. 6).

- 2. These GSK-specific definitions of WAC (and WAC equivalents)<sup>2</sup> were widely shared outside of the company, including with First DataBank. *See* Collection of GSK price reporting letters produced from First DataBank's files appended as Exs. 5, 7 and 8.
- 3. GSK's definitions of WAC (and WAC equivalents) are entirely consistent with the definition of WAC as a "list price" that does not include discounts, which was set forth in numerous publications (including OIG reports and other government publications provided to state Medicaid agencies) as early as 1997. See, e.g., HHS OIG Report: Cost Containment of Medicaid HIV/AIDs Drug Expenditures, OEI-05-99-00611 at 5-7 (2001) (states that "for brand name drugs, manufacturers set the wholesale acquisition price as a list price for wholesalers to purchase drugs from manufacturers. ... Both the WAC and the AWP operate as suggested list prices and are typically not what is paid. Buyers negotiate lower prices through the inclusion of discounts, rebates or free goods" (pp. 5-6); also contains a chart referring to WAC as a "list price" and AMP as the corresponding actual selling price for Medicaid (p. 7)) (relevant portions appended as Ex. 10); GAO Report: Medicare – Payments for Covered Outpatient Drugs Exceed Providers' Cost, at 23 (2001) (states that "WAC is the list price a wholesaler pays to a manufacturer, but it does not include discounts that may affect the net price") (relevant portions appended as Ex. 11); E.M. (Mick) Kolassa, Elements of Pharmaceutical Pricing at 33 (1997) (states that "Wholesale Acquisition Cost (WAC) ... is used by some publishers of pricing data to denote the ex-factory charge, before discounts, to the wholesaler") (relevant portions appended as Ex. 12).

For ease of reference, we sometimes use "WAC" in this GSK Statement of Facts to refer to both WAC and WAC equivalents such as NWP and WPP. We also sometimes use "GSK" to refer to both GSK and its predecessor companies.

- 4. GSK's definitions of WAC (and WAC-equivalents) are also consistent with the statutory definition of WAC that was enacted into the federal Medicare and Medicaid statutes in December 2003. That statute defines WAC as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price . . .." 42 U.S.C. § 1395w-3a (c) (6) (B) (Medicare Modernization Act); see 42 U.S.C. § 1396r-8(b)(3)(A)(iii)(II) (incorporation of the MMA WAC definition into the Medicaid rebate statute).
- 5. To determine an AWP for GSK's and GSK predecessors' drugs during the 1997-2005 period, the price reporting services have chosen and applied a standard markup to the company's reported WAC list price. The mark-up has been either 1.20 or 1.25 depending on the particular drug, the time period and the reporting service. Moules 2006 Aff. at ¶¶ 4-7 (Ex. 6). From 1997 until after GSK was formed, the pricing publications typically published an AWP for GW products that was 1.20 times the WAC-equivalent that GW reported. Id. at ¶ 4. During that same period, the pricing publications typically published an AWP for SB products that was 1.25 times the WAC-equivalent that SB reported. Id. at ¶ 5. Since 2002, the AWPs that have been published for GSK products have differed between the major commercial price reporting publications. Since 2002 the Redbook, for example, has generally published an AWP for GSK products that is 1.20 times GSK's reported WAC, whereas First DataBank has generally published an AWP for GSK products that is 1.25 times GSK's reported WAC. These differing decisions concerning what AWPs to publish for GSK products, and what ratio should be applied to the WACs reported by GSK in order to derive those AWPs, were made by the price reporting services, not by GSK. *Id.* at ¶ 7; Moules 2004 Aff. at ¶¶ 5-11 (Ex. 3).

- B. Litigation and Settlement of Prior Pharmaceutical Pricing Litigation
  Filed Against GSK by the State of New York
- 6. In February 2003, the State of New York filed a pharmaceutical pricing complaint against GSK that made the same general allegations concerning the pharmaceutical list prices GSK reported as those now being asserted in this case by the New York Counties. See Complaint in The People of the State of New York, by Eliot Spitzer, Attorney General of the State of New York, v. GlaxoSmithKline, plc. et. al., Index No. 905-03 (Sup. Ct. N.Y., February 13, 2003) (the "State of New York Case") (appended as Ex. 13).
- 7. The Complaint in the State of New York case correctly alleged that GSK and its predecessors reported WACs and WAC-equivalents to the national drug pricing services, and that those services applied a "standard markup" to GSK's reported prices to determine the AWPs for GSK's products. *Id.* at ¶ 15, 17 (Ex. 13).
- 8. The State further alleged that GSK's WACs for products covered by the New York Medicaid Program (as well as those covered by Medicare Part B) were fraudulently inflated -- resulting in inflated AWPs which were in turn used by the New York Medicaid Program to reimburse for GSK's drugs. *Id.* at ¶¶ 22, 28-29. Like the county plaintiffs here, the State of New York alleged, among other claims, that GSK violated New York's Deceptive Acts and Practices statute (N.Y. General Business Law § 349) and the New York statute prohibiting false statements to obtain public funds, N.Y. Social Services Law § 145-b. *Id.* at ¶ 3; and *Id.* at First and Fifth Causes of Action.
- 9. The State of New York's case against GSK was vigorously litigated for more than three years. During that litigation, GSK provided the State with detailed GSK sales transaction data for a large number of GSK drugs and NDCs (both self-administered

and physician-administered) covered by the New York Medicaid program. See 3/28/05 GSK discovery letter, appended as Ex. 14, and Herold Aff. at ¶ 13 (Ex. 1).

- 10. After extensive analysis of the actual transaction prices at which GSK sold its drugs, including analysis of the discounts, rebates and chargebacks contained within GSK's data systems, the State of New York and GSK reached a settlement agreement that resolved the case in its entirety. The agreement was filed with the Supreme Court of the State of New York (County of Albany) as a Consent Order and Judgment on August 14, 2006. *See* Consent Order and Judgment, appended as Ex. 15, and Herold Aff. at ¶ 14 (Ex. 1).
- million in Medicaid-related payments for certain NDCs of just three GSK drugs Kytril and Zofran injectibles (both physician-administered drugs that were subject to a prior settlement with the Department of Justice) and Amoxil (an off-patent multi-source drug). Consent Order and Judgment at Section II 3(a), Section III. 1 and Attachment 2 (Ex. 15). Due to unique circumstances, these drugs were historically sold by GSK at significantly discounted prices. In exchange for GSK's settlement payments, the State of New York dismissed all claims related to Kytril and Zofran injectibles and certain Amoxil NDCs with prejudice, and provided a release that explicitly covered claims for those drugs by "New York or any of its counties." *Id.* at Section III. 6(a) and (8) and Attachment 2 (Ex. 15).
- 12. In addition, after a comprehensive evaluation of GSK's pricing practices and the asserted claims with respect to all *other* GSK drugs reimbursed by New York Medicaid (referred-to in the settlement agreement as "Medicaid Other Drug Claims"), the State of New York dismissed its claims for all of these "other drugs" without receiving

any settlement payments relating to them -- but this dismissal was "without prejudice."

Id. at Section II 3 (b) and Section III. 6(b) (Ex. 15); Herold Aff. at ¶ 14. The State of New York settlement agreement also provided, among other things, that GSK would report certain certified pricing information (including AMPs) directly to the State of New York's Medicaid Program for all drugs covered by Medicaid, including those subject only to dismissal without prejudice in that case. Consent Order and Judgment at Section III. 2 and Addendum A (Ex. 15). This ended the State's WAC/AWP lawsuit against GSK.

- C. The Claims Against GSK in the New York Counties' Revised First Amended Consolidated Complaint
- 13. Although the WAC/AWP claims of the New York Counties in this lawsuit have been pled, dismissed and repled several times, those that remain against GSK are substantively the same as the claims previously asserted against GSK by the State of New York. The Counties allege, with respect to WAC reporters like GSK, that the reported WACs (or WAC equivalents) for Medicaid-covered drugs were "false and inflated," and that "drug manufacturers know that by reporting a false and inflated WAC or WAC equivalent they can trigger the publication of a false and inflated AWP on which reimbursements are made." Revised First Amended Consolidated Complaint ("hereinafter RFACC") at ¶ 12.
- 14. The New York Counties allege, through Exhibits A and B-18 of the RFACC, that the reported WACs for 270 GSK NDCs (as well as the published AWPs that were allegedly "caused" by these WACs) were false and inflated.<sup>3</sup>

The RFACC exhibit that lists the GSK drugs at issue (Exhibit B-18) lists two GSK NDCs -- one for Amoxil 500mg capsules (NDC 00029600732) and one for Zofran 2mg/ml vials (NDC 00173044200) -- that were subject to the New York State settlement agreement's explicit release. It also lists six NDCs for Ceftin, which are not GSK NDCs; those NDCs were for a time-period during which GSK did not distribute or report prices for Ceftin. The two settled NDCs and six Ceftin NDCs distributed

- 15. On the basis of these allegations, the New York Counties assert that GSK violated New York's Deceptive Acts and Practices statute (N.Y. General Business Law § 349) (Count VI) and the New York statute prohibiting false statements to obtain public funds, N.Y. Social Services Law § 145-b (Count III) -- both of which were asserted in the New York State case. They also assert a common law fraud claim (Count VII).<sup>4</sup>
  - D. There Has Been Extensive Discovery In This Case With Respect to GSK's Medicaid-Covered Drugs.
- 16. Although this Court stayed discovery with respect to drugs alleged by the Counties to have "spreads" between acquisition cost and published AWP of 30% or less, GSK has nevertheless produced voluminous data and documents to the New York Counties with respect to virtually all of its Medicaid-covered drugs. On April 18, 2007, GSK entered into a Stipulation with the New York Counties under which it agreed to make the same "GSK Core Documents" and data available to the New York Counties as it produced in multiple other AWP cases around the country, and under which the parties also agreed that GSK's key Rule 30(b)(6) depositions would be cross-noticed in this case. See Stipulation appended as Ex. 4 and Herold Aff. at ¶ 3(Ex. 1).
- 17. Pursuant to that Stipulation, GSK has produced detailed sales transaction data for its Medicaid-covered drugs to the New York Counties, as well as a massive quantity of documents (including documents produced in the MDL class action, depositions taken in that case, and multiple productions of documents produced in other state AWP cases). See two GSK discovery letters to Joanne Cicala dated April 18, 2007 (appended as Ex. 16); see also GSK discovery letters to Joanne Cicala dated, June 13,

by a non-GSK entity were not analyzed under the WAC List Price test discussed below. See Affidavit of Dr. Eric M. Gaier at ¶4, fn. 1 (Ex. 2).

The Counties also asserted other WAC/AWP claims, but they were dismissed by this Court's Memorandum and Order dated April 2, 2007 and were included in the RFACC only for appellate purposes.

2007, February 28, 2008 and June 30, 2008, appended together as Ex. 17, and Herold Aff. at ¶¶ 15-16 (Ex. 1).

- 18. Between the voluminous discovery that GSK has produced to date and the data and documents otherwise available to the New York Counties (e.g., prices published by the commercial price reporting services, wholesaler data and Medicaid claims data), the New York Counties have long had the data and documents necessary to evaluate their claims under applicable legal standards for all of the GSK drugs they are seeking to place at issue in this case.
  - E. The Vast Majority of GSK's Sales to Its Customers Were Within 5% of GSK's Reported WAC List Price.
- 19. Dr. Eric M. Gaier, a Ph.D. economist who has previously testified before this Court as an expert in the AWP cases, has analyzed GSK's sales transaction data for 262 GSK NDCs at issue in this case (*see* note 3, *supra*) to determine what percentage of sales for each NDC were made by GSK at or about GSK's reported WAC list prices. The results of Dr. Gaier's analysis are presented, in detail, in the Affidavit of Dr. Eric M. Gaier ("hereinafter Gaier Aff.") and in exhibits accompanying his affidavit, collectively appended hereto as Ex. 2.
- 20. To determine what percentage of GSK's sales were "at or about" GSK's WAC list prices, Dr. Gaier conservatively applied the guidelines set forth in this Court's decision concerning whether WAC list prices were deceptive. See In Re Pharmaceutical Industry Average Wholesale Price Litigation, 491 F. Supp. 2d 20, 104-06 (D. Mass. 2007).
- 21. Dr. Gaier analyzed GSK's transaction-by-transaction sales, rebate and chargeback data for all of the NDCs at issue for the period 1997-2005, on an NDC-by-NDC, year-by-year basis. His universe included every GSK commercial U.S. sale to

every class of trade (i.e., every transaction other than those involving charities, samples or returns). Gaier Aff. at ¶ 6-7 (Ex. 2).

- 22. In addition, in order to be conservative in determining the GSK customers' transaction prices net of all discounts, rebates and chargebacks, Dr. Gaier (a) reduced each sale transaction price by 2% based on an assumption that a 2% prompt-pay discount was paid for *all* of GSK's direct sales to wholesalers or providers, and (b) calculated transaction prices by taking into account *all* discounts and rebates given to customers and *all* chargebacks credited as the result of contracts with customers. Gaier Aff. at ¶¶ 6-7 (Ex. 2).
- 23. Dr. Gaier followed this Court's decision and concluded that a transaction price was "at or about" WAC only if it was within 5% of the applicable WAC list price.

  Id.; see 491 F. Supp. at 106-08. For each NDC, he determined the percentage of the total number of units sold each year that had a transaction price within 5% of the WAC list price. For purposes of this motion, the NDC was deemed to have "passed" the WAC List Price test if (after appropriate weighting) more than 50% of the total number of units sold had a transaction price within 5% of the reported WAC. Gaier Aff. at ¶ 6-7 (Ex. 2).
- 24. The overall results of Dr. Gaier's "WAC List Price" analysis for the GSK drugs at issue in this case are summarized in Attachment B to his Affidavit (Ex. 2). The detailed year-by-year, NDC-by-NDC breakdown that went into the "WAC List Price" analysis summarized in Attachment B of the Gaier Affidavit is set forth in Attachment D to his Affidavit (Ex. 2). Table D.1 provides the detailed back-up that went into the summary in Table B.1 for the 208 NDCs for which GSK now moves for summary judgment.

- 25. For 208 of the GSK NDCs at issue here -- listed in Table B.1 -- the percentage of sales with transaction prices within 5% of WAC is over the 50% threshold for the relevant period, and for the vast majority of these NDCs the percentage is higher than 80% or even 90%. Gaier Aff. at Table B.1 (Ex. 2).<sup>5</sup>
- 26. To further demonstrate the impact that the WAC List Price test has on plaintiffs' claims in this case, Dr. Gaier also compared the alleged New York Medicaid reimbursement amounts associated with the GSK drugs that pass the WAC List Price test to the total alleged reimbursements for all of the GSK drugs at issue here. Gaier Aff. at ¶ 7 (Ex. 2). Of the approximately \$2.143 billion that the New York Counties allege was reimbursed in total for the 262 GSK NDCs analyzed by Dr. Gaier here (a total which includes the New York county, state and federal shares), Dr. Gaier determined that 98.3% (\$2.107 billion) of these alleged expenditures relate to the 208 GSK NDCs where more than 50% of the sales for the relevant period were made at transaction prices within 5% of the reported WAC list price. *Id*.
- 27. In addition, although GSK is not presently moving for summary judgment on the basis of the AWP "spreads" of its drugs, Dr. Gaier has examined those spreads and has conservatively determined that for the vast majority of the GSK NDCs in this case the spreads are less than 30%. Just as was done for other manufacturers in the Track One MDL trial, Dr. Gaier examined GSK's spreads on an NDC-by-NDC, year-by-year basis and calculated the "spread" percentages as a mark-up from the acquisition cost

Table B.2 of Dr. Gaier's Affidavit (Ex. 2) presents the remaining GSK drugs for which less than 50% of the sales -- when assessed either by units sold or dollars sold -- were at transaction prices within 5% of WAC. GSK is not moving for summary judgment on these NDCs at this time. All of them are relatively small-volume products -- most had alleged total New York Medicaid reimbursements over the nine-year period at issue of less than \$100,000.

Because GSK is not moving for summary judgment on the basis of the AWP "spreads" of its drugs, the facts relating to those "spreads" are not "material" for purposes of the instant motion.

(instead of as a discount from the AWP). Gaier Aff. at ¶8 (Ex. 2). As set forth in Dr. Gaier's affidavit, he was instructed to apply a number of conservative assumptions for purposes of this exercise, so as to avoid potential factual disputes. The overall results of Dr. Gaier's AWP "spread" analysis for the GSK NDCs at issue in this case are summarized in Attachment C to his affidavit (Ex. 2). For all of the NDCs in Table C.1 -- which account for more than 99% of the New York Counties' alleged expenditures for the GSK drugs in this case -- the "spread" is less than or equal to 30% for the relevant period. See Gaier Aff. at ¶¶ 8-9 and Table C.1 (Ex. 2). In Attachment E to Dr. Gaier's affidavit, he sets forth the NDC-by-NDC, year-by-year AWP "spread" analysis which formed the basis for the overall results set forth in the summary contained in Attachment C. Id at Attachment E (Ex. 2).

28. With respect to the GSK NDCs for which GSK *is* moving for summary judgment now (*i.e.*, those which pass the WAC List Price test for the relevant period) all but four (out of 208) of them *also* have AWP "spreads" for plaintiffs' alleged Medicaid classes of trade that are less than or equal to 30%. Dr. Gaier has placed an asterisk in the column on Table B.1 entitled "Percentage of sales units 'at or about' WAC" to indicate that that particular NDC *also* has an AWP "spread" for the relevant period of 30% or less. Gaier Aff. at ¶ 10 and Table B.1 (Ex. 2); *see also* asterisks on year-by-year analysis presented in Gaier Aff. Table D.1 (Ex. 2).

Dated: November 24, 2008 Respectfully submitted,

Defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK")

By its attorneys,

/s/ Frederick G. Herold

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## **CERTIFICATE OF SERVICE**

I hereby certify that today I have caused an electronic copy of the foregoing Statement of Undisputed Material Facts In Support of SmithKline Beecham Corporation, d/b/a GlaxoSmithKline's ("GSK's) Motion for Partial Summary Judgment in the New York County Cases, along with all exhibits referenced therein, to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL No. 1456 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: November 24, 2008 /s/ Frederick G. Herold

Frederick G. Herold